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PATENT
Customer No. 22,852
Attorney Docket No. 08888.0530-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Patrick BENOIT et al.)
Application No.: 10/005,337) Group Art Unit: 1635
Filed: December 7, 2001) Examiner: Terra C. Gibbs
For: SEQUENCES UPSTREAM OF THE)
CARP GENE, VECTORS CONTAINING)
THEM AND USES THEREOF)

RECEIVED

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

OCT 23 2003

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Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement mailed September 23, 2003, the Examiner required restriction under 35 U.S.C. § 121 among the following groups:

Group I. Claims 1-39, allegedly drawn to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1, an expression cassette comprising a sequence encoding a protein or an RNA linked to said polynucleotide, and a vector comprising said expression cassette, classifiable in class 536, subclass 24.5.

Group II. Claims 1-39, allegedly drawn to a polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2, an expression cassette comprising a

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

sequence encoding a protein or an RNA linked to said polynucleotide, and a vector comprising said expression cassette, classifiable in class 536, subclass 24.5.

- Group III. Claims 34 and 35, allegedly drawn to a transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1, classifiable in class 800, subclass 3.
- Group IV. Claims 34 and 35, allegedly drawn to a transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2, classifiable in class 800, subclass 3.
- Group V. Claims 37 and 38, allegedly drawn to a method for expressing a protein or an RNA in cells *in vivo*, comprising administering an expression cassette comprising a sequence encoding a protein or an RNA linked to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1, classifiable in class 514, subclass 44.
- Group VI. Claims 37 and 38, allegedly drawn to a method for expressing a protein or an RNA in cells *in vivo*, comprising administering an expression cassette comprising a sequence encoding a protein or an RNA linked to a polynucleotide comprising a fragment of SEQ ID

NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2, classifiable in class 514, subclass 44.

Applicants respectfully advise the Examiner that the listing of claims corresponding to the alleged inventions appears to be incorrect. For example, the Examiner asserts that claims 1-39 are properly included in Group I, drawn, *inter alia*, to a polynucleotide comprising a fragment of SEQ ID NO:1. Office Action mailed September 23, 2003, at 2. The Examiner also contends that claims 1-39 are properly included in Group II, drawn, *inter alia*, to a polynucleotide comprising a fragment of SEQ ID NO:2. *Id.* However, a review of claims 1-39 shows that only claims 1-3, 6, 8, 10, 12, 13, 16, 18, 20, 22, 24, 26, 28, 30, 32, and 38 recite a polynucleotide comprising a fragment of SEQ ID NO:1, and that only claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39 recite a polynucleotide comprising a fragment of SEQ ID NO:2. Applicants believe that the Examiner intended the following: Group I (claims 1-3, 6, 8, 10, 12, 13, 16, 18, 20, 22, 24, 26, 28, 30, 32, and 38), Group II (claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39), Group III (claim 34), Group IV (claim 35), Group V (claim 36), and Group VI (claim 37) and have replied accordingly.

Applicants provisionally elect to prosecute Group I, claims 1-3, 6, 8, 10, 12, 13, 16, 18, 20, 22, 24, 26, 28, 30, 32, and 38, allegedly drawn to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1, an expression cassette comprising a sequence encoding a protein or an RNA linked to said polynucleotide, and a vector comprising said expression cassette, with traverse. In particular, Applicants respectfully request the reconsideration and withdrawal of the requirement for restriction between Group I and Group II, which is

allegedly drawn to a polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2, an expression cassette comprising a sequence encoding a protein or an RNA linked to said polynucleotide, and a vector comprising said expression cassette.

The Examiner acknowledges that the compositions of Groups I and II are related to each other because they are drawn to a polynucleotide. *Id.* at 4. Nevertheless, the Examiner asserts that restriction is proper because Group I employs SEQ ID NO:1 and Group II employs SEQ ID NO:2. *Id.* The Examiner asserts that a search of the polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO: 1 of Group I would not encompass all of the art relevant to the polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO: 2 of Group II. *Id.* at 4-5.

According to the M.P.E.P.,

... each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.* Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

M.P.E.P. § 803.04.

In addition, "in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." *Id.*

Applicants respectfully submit that restriction between inventions encompassing SEQ ID NO:1 and inventions encompassing SEQ ID NO:2 conflicts with the Commissioner's decision as embodied in M.P.E.P. § 803.04. This is especially true where, as here, the Examiner requires restriction between inventions encompassing homologs derived from different species. Applicants request withdrawal of the restriction requirement between Groups I and II.

Applicants also respectfully request the reconsideration and withdrawal of the requirement for restriction between Groups III and IV and between Groups V and VI. The requirement for restriction between these groups also appears based on the recitation of SEQ ID NO:1 and SEQ ID NO:2. Again, Applicants respectfully submit that requiring restriction on this basis conflicts with M.P.E.P. § 803.04.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 20, 2003

By: 
William L. Strauss
Reg. No. 47,114

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com